SEP - 5 2001

510(k) SUMMARY

K012573

Castle® 400HC/500HC Series Steam Sterilizer
Models: 422HC, 433HC, 522HC, and 533HC

Submitted by: Getinge/Castle Inc.
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Date prepared: August 31, 2001

Proprietary Name: Castle® 400HC/500HC Series Steam Sterilizer
Models: 422HC, 433HC, 522HC and 533HC

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80 FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Castle® Series 100HC Steam Sterilizer [K994314]

Description of Device:

The 400HC/500HC Series Steam Sterilizer is intended for use in hospital and health care facilities. The product incorporates an update to the control system that provides additional functionality and ease of use to the end user. It includes a larger color display that will allow the user to choose from the entire list of available cycles. Similar features to those on the Series 100HC include renaming and re-sequencing of sterilization cycles. The full lists of available cycles are provided in Table 1 for vacuum sterilizers (Models 433HC and 533HC) and Table 2 for gravity sterilizers (Models 422HC and 522HC).

(Continued...)

Table 1. Model 433HC and 533HC Vacuum Steam Sterilizer Cycles and Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration[2]	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time[1]		433HC	533HC
GRAVITY 1 (grv)	3	250°F (121°C)	30 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
Flash 3+ (f 3)	4	275°F (135°C)	3 min.	10 sec.[5]	• Unwrapped non-porous single instrument • Unwrapped non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
Flash 10+ (f10)	2	275°F (135°C)	10 min.	10 sec.[5]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
PREVAC 1 (vac)	3	275°F (135°C)	3 min.	16 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
PREVAC 2 (vac)	2	275°F (135°C)	3 min.	3 min.	• Single wrapped single instrument • Single wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	1 2 4	1 3 12
PREVAC 3 (vac)	1	275°F (135°C)	3 min.	0 min.[5]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
Bowie-Dick Test (vac)	1	273°F (134°C)	3 min. 30 sec.	0 min.	S.M.A.R.T. Pack or equivalent (1 max.) in an EMPTY chamber	1 Test Pack	1 Test Pack
Vacuum Leak Test (lkt)[3]	1	268°F (131°C)	3 min.	15 min. dry 5 min. dwell 15 min. test	Empty chamber	--	--
LIQUIDS1 (liq)	1	250°F (121°C)	30 min.	0.75 psi/min.[4]	Up to 250 mL containers	80	168
LIQUIDS2 (liq)	1	250°F (121°C)	45 min.	0.75 psi/min.[4]	Up to 1000 mL containers	15	32

Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

[1]Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase.

[2]Refer to AAMI Standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization — Steam Sterilization of Patient Care Items for Immediate Use.*

[3]Vacuum leak test cycle parameters are not adjustable.

[4]Cooldown rate

[5]Items may NOT be dry. Dry time may be added if required.

Table 2. Model 422HC and 522HC Gravity Steam Sterilizer Cycles an Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration[2]	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time[1]		422HC	522HC
GRAVITY 1 (grv)	3	250°F (121°C)	30 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
Flash 3+ (f 3)	4	275°F (135°C)	3 min.	10 sec.[4]	• Unwrapped non-porous single instrument • Unwrapped non-porous instru ment trays, up to 16 lbs. per tray.	1 2	1 2
Flash 10+ (f10)	2	275°F (135°C)	10 min.	10 sec.[4]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
LIQUIDS1 (liq)	1	250°F (121°C)	30 min.	0.75 psi/min.[3]	Up to 250 mL containers	80	168
LIQUIDS2 (liq)	1	250°F (121°C)	45 min.	0.75 psi/min.[3]	Up to 1000 mL containers	15	32

Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

[1]Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase.

[2]Refer to AAMI Standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use.*

[3]Cooldown rate

[4]Items may NOT be dry. Dry time may be added if required.

Intended Use:

Castle® 400HC/500HC Series Steam Sterilizers are intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Predicate Device

Castle® Series 100HC Steam Sterilizer [K994314].

Nonclinical Comparisons to Predicate Device

The 400HC/500HC Series Steam Sterilizer is a family name and includes new model number designations to identify incorporation of various design improvements and sterilizer control system. These sterilizers are similar to the Series 100HC predicate device. Modifications made from the predicate device include:

- Control System is updated to use an improved CPU and user interface. The new user interface includes a larger color display that provides information to be presented more completely and in a clear format. Adjustments have also been made to password features.
- Software is updated for use within the new control system.
- Sterilizer chamber has changed from having a full jacket to a partial jacket with a material change from nickel clad to stainless steel.
- Increased the number of available pre-validated cycles.
- Piping is modified for incorporation with new pressure vessel design.

Clinical Data:

No clinical data is required for this submission.

Conclusion:

The Castle® 400HC/500HC Series Steam Sterilizer is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology, intended use of this device. This sterilizer meets the applicable requirements of AAMI ST8, CSA-Z314.7, GGS-1340A and GGS-1343A Standards.

Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2001

Mr. Frederick R. Catt
Sr. Regulatory Compliance Engineer
Getinge/Castle, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K012573
Trade/Device Name: Castle 400HC/500HC Series Steam Sterilzer, Models 422HC, 433HC, 522HC and 533HC
Regulation Number: 880.6880
Regulatory Class: II
Product Code: FLE
Dated: August 8, 2001
Received: August 9, 2001

Dear Mr. Catt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K012573

Device Name: **Castle® 400HC/500HC Series Steam Sterilizer**
Models: 422HC, 433HC, 522HC and 533HC

Indications for Use:

Castle® 400HC/500HC Series Steam Sterilizer is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Table 1. Model 433HC and 533HC Vacuum Steam Sterilizer Cycles and Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration[2]	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time[1]		433HC	533HC
GRAVITY 1 (grv)	3	250°F (121°C)	30 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
Flash 3+ (f 3)	4	275°F (135°C)	3 min.	10 sec.[5]	• Unwrapped non-porous single instrument • Unwrapped non-porous instru ment trays, up to 16 lbs. per tray.	1 2	1 2
Flash 10+ (f10)	2	275°F (135°C)	10 min.	10 sec.[6]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
PREVAC 1 (vac)	3	275°F (135°C)	3 min.	16 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
PREVAC 2 (vac)	2	275°F (135°C)	3 min.	3 min.	• Single wrapped single instrument • Single wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	1 2 4	1 3 12
PREVAC 3 (vac)	1	275°F (135°C)	3 min.	0 min.[5]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
Bowie-Dick Test (vac)	1	273°F (134°C)	3 min. 30 sec.	0 min.	S.M.A.R.T. Pack or equivalent (1 max.) in an EMPTY chamber	1 Test Pack	1 Test Pack
Vacuum Leak Test (lkt)[3]	1	268°F (131°C)	3 min.	15 min. dry 5 min. dwell 15 min. test	Empty chamber	--	--
LIQUIDS1 (liq)	1	250°F (121°C)	30 min.	0.75 psi/min.[4]	Up to 250 mL containers	80	168
LIQUIDS2 (liq)	1	250°F (121°C)	45 min.	0.75 psi/min.[4]	Up to 1000 mL containers	15	32

Notes for Table 1:

Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

[1]Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase.

[2] Refer to AAMI Standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization — Steam Sterilization of Patient Care Items for Immediate Use.*

[3]Vacuum leak test cycle parameters are not adjustable.

[4]Cooldown rate

[5]Items may NOT be dry. Dry time may be added if required.

Table 2. Model 422HC and 522HC Gravity Steam Sterilizer Cycles and Load Chart

Cycle Type	No. of Available Cycles	Factory Settings			Load Configuration[2]	Maximum Items per Chamber Size	
		Exp. Temp.	Exp. Time	Dry Time[1]		422HC	522HC
GRAVITY 1 (grv)	3	250°F (121°C)	30 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
GRAVITY 2 (grv)	3	275°F (135°C)	10 min.	30 min.	• Double-wrapped instrument trays, up to 16 lbs. per tray. • Fabric packs	2 4	3 12
Flash 3+ (f 3)	4	275°F (135°C)	3 min.	10 sec.[4]	• Unwrapped non-porous single instrument • Unwrapped non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
Flash 10+ (f10)	2	275°F (135°C)	10 min.	10 sec.[4]	• Unwrapped porous or non-porous single instrument • Unwrapped porous & non-porous instrument trays, up to 16 lbs. per tray.	1 2	1 2
LIQUIDS1 (liq)	1	250°F (121°C)	30 min.	0.75 psi/min.[3]	Up to 250 mL containers	80	168
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Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

[1]Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions. Gravity cycle drying time may be reduced by selecting vacuum drying phase.

[2]Refer to AAMI Standards ST46 *Good Hospital Practice: Steam Sterilization and Sterility Assurance* and ST37 *Good Hospital Practice: Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use.*

[3]Cooldown rate

[4]Items may NOT be dry. Dry time may be added if required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012573